

National Cancer Institute Cancer Therapy Evaluation Program Common Data Elements

Presentation to the National Cancer Institute
Cancer Biomedical Informatics Grid

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Overview

- Where we came from
 - Arising from the primordial acronym soup
- Evolution
 - Walking upright, using tools, building communities
- Where are we going
 - To infinity and beyond

NCI's Call for Standards

- “Report of the National Cancer Institute Clinical Trials Program Review Group”
a.k.a. “Armitage Report”
 - August 1997
 - Call for uniform data collection
 - to promote efficient protocol implementation
 - to enhance the ability to share and compare data

NCI CTEP CDE Initiative

- Cancer Therapy Evaluation Program (CTEP) Common Data Element (CDE) initiative
 - launched in 1997
 - to standardize questions and values on case report forms (CRFs)

What is a Common Data Element?

- Standardized terms for the collection and exchange of data
- Metadata
 - attributes
 - relationships
- CTEP perspective
 - CDE represents CRF question and includes permissible values

Cancer Data Standards Repository (caDSR)

- Developed by NCICB
- Repository for NCI CDEs
- Based on *ISO/IEC 11179: Specification and Standardization of Data Elements*

Current caDSR Contexts with Common Data Elements

Context Name

of CDEs

➤ Cancer Therapy Evaluation Program (CTEP)	7454
➤ caCORE	909
➤ Specialized Programs of Research Excellence (SPORES)	619
➤ NCI Center for Cancer Research (CCR)	548
➤ NCI Division of Cancer Prevention (DCP)	331
➤ Cancer Imaging Project (CIP)	213
➤ Early Detection Research Network (EDRN)	127
➤ Cancer Biomedical Informatics Grid (caBIG)	49
➤ Norris Cancer Center (NORRIS)	1

Goals of CTEP's CDE Initiative

- Well-defined terminology
- Consistent data collection
- Data reduction
- Consistent analysis and meta-analysis
- Error reduction
- Data sharing

CTEP's CDE Development Process

- Collaborative committee process
- Consideration given to existing terms and standards
- Result is identification, standardization, definition, and classification of CDEs
- Mandated use on CRFs
- Identification of potential CDEs through CRF review

Current CTEP CDE Collection

- Bladder cancer
- *Brain cancer (primary site and metastases)*
- Breast cancer
- Colorectal cancers
- Gynecologic cancers
- *Head and neck cancers*
- Leukemia
- Lung cancer
- *Lymphoma*
- Melanoma
- *Multiple myeloma*
- Prostate cancer
- *Sarcoma*
- Upper GI cancers
- Pathology
- Specimen banking

Stakeholders

- Collaborators in development
 - CTEP
 - Clinical Trials Cooperative Group Program
 - Specialized Programs of Research Excellence
 - Cancer Biomarkers Research Group
 - Early Detection Research Network
 - NCI Center for Bioinformatics
 - The Oracle Corporation
 - The EMMES Corporation
 - ScenPro
- Primary constituents
 - Clinical Trials Cooperative Groups
 - Cancer Trials Support Unit

Case Report Forms

Colorectal Sx Form Final.doc - Microsoft Word

File Edit View Insert Format Tools Table Window Help

Normal Times New Roman 10 B I U

Are data amended? (if data are amended, please circle in red when using paper form) ☐ Yes ☐ No

Colorectal: Surgical Procedure

Surgical Procedure Description (complete a separate surgical form for each surgical procedure)

Surgery Date
MM DD YYYY

Did the patient receive Prior Radiation Therapy? ☐ Yes ☐ No ☐ Unknown

Did the patient receive Prior Systemic Chemotherapy? ☐ Yes ☐ No ☐ Unknown

Did the patient receive Prior Immunotherapy? ☐ Yes ☐ No ☐ Unknown

Location of Tumor(s)
(check all that apply, but only one box for each tumor)

☐ Appendix ☐ Sigmoid

☐ Ascending colon ☐ Splenic flexure

☐ Cecum ☐ Transverse colon

☐ Descending colon ☐ Rectum

☐ Hepatic flexure ☐ Other, specify _____

Surgical Approach (check only one)

☐ Left colectomy ☐ Abdominal perineal resection

☐ Right colectomy ☐ Low anterior resection

☐ Transverse colectomy ☐ Sphincter-preserving rectal re.

☐ Total colectomy ☐ Sigmoidectomy

Was there bowel Perforation? ☐ No ☐ Yes ☐ Unknown

Was there bowel Obstruction? ☐ No ☐ Yes ☐ Unknown

Page 1 Sec 1 1/2 At 4.5" Ln 19 Col 15 REC TRK EXT OVR English (U.S.)

Valid Values

Data Element

Compliance Review Results

Microsoft Excel - Sample Question Comparison Report.xls

File Edit View Insert Format Tools Data Window Help

Tahoma 10 B I U

A1 = Group CRF Name

	A	B	C	D	E	F	G	H	I	J
	Group CRF Name	Group CRF Question	Affiliated Valid Value?	NCI CDE Identifier	CDE Version	CDE Document Text	CDE Long Name	Historic Short CDE Name	Match?	Reviewer Comments
2	Sample Follow-up Form	Institution Name	N	2005790	4	Institution Name	Institution Name	Institution	Exact Match	
3	Sample Follow-up Form	NCI Number	N	59	3	NCI Protocol Number	Protocol NCI Identifier Number	NCI Protocol Number	Recommended Term	
4	Sample Follow-up Form	Patient ID	N	782	4	Coordinating Group Patient ID	Patient Coordinating Identifier Number	Patient Study ID	Recommended Term	
5	Sample Follow-up Form	Patient Initials	N	2001039	4	Pt Initials	Patient Initials Name	Patient Initials	Exact Match	
6	Sample Follow-up Form	Today's date	N	2005343	3	Date Form Originally Completed	Form Original Complete Date	Form Completion Date, Original	Recommended Term	
7	Sample Follow-up Form	Reporting Period Start Date	N	2993	4	Reporting Period Start Date	Treatment Reporting Period Begin Date	Interval Report From Date	Exact Match Approved	
8	Sample Follow-up Form	Reporting Period End Date	N	2992	4	Reporting Period End Date	Treatment Reporting Period End Date	Interval Report To Date	Exact Match Approved	
9	Sample Follow-up Form	Life status at the end of this reporting period	Y	2005378	3	Vital Status	Patient Vital Status	Patient's Vital Status	Recommended Term	
10	Sample Follow-up Form	Date of Death	N	2005958	3	Date of Last Contact or Death	Patient Last Contact Date	Death Date/Last Contact Date	Recommended Term	
11	Sample Follow-up Form	Contributing Cause of Death	Y	2006031	1	Contributing Cause of Death	Patient Death Reason		Recommended Term	Please see recommended changes for valid values.
12	Sample Follow-up Form	please specify [contributing cause of death]	N	2751	5	Describe cause of death	Patient Death Specify	Death Reason, Specify	Recommended Term	
13	Sample Follow-up Form	Primary cause of Death	Y	1268	5	Primary Cause of Death	Patient Death Primary Reason	Death Reason	Recommended Term	Please see recommended changes to valid values.
14				2751	5			Death Reason, Specify	Recommended Term	
15				2006020	5			Primary Cancer Ind	Exact Match Approved	
16				631	4			Primary Cancer Date	Recommended Term	
17	Sample Follow-up Form	Was the patient confirmed lost to follow-up at the end of this reporting period?	Y	2006035	3	Was patient unable to be contacted for current scheduled follow-up?	Patient Lost Follow-up Ind-2	Lost to Follow-Up	Recommended Term	
18	Sample Follow-up Form	Did the patient withdraw consent for follow-up at the end of the reporting period?	Y	2006034	1	Did the patient withdraw consent for follow-up at the end of the reporting period?	Patient Follow-up Consent Withdrawn Ind-2		Draft New	
19	Sample Follow-up Form	Did the patient receive non-protocol anti-cancer treatment during this reporting period?	Y	2005930	3	Is the patient receiving any non-protocol cancer therapy not previously reported?	Non-protocol Therapy Administered Ind-3	Non-Protocol Therapy Ind	Recommended Term	
20	Sample Follow-up Form	Comments	N	2005808	5	Comments	Research Comments Text	Comments	Exact Match	

CRF Question

CDE Question

caDSR Tools of the Trade

- CDE Browser
 - <http://ncicb.nci.nih.gov/CDEBrowser/>
- caDSR Administration Tool
- Curation Tool
- CDE Compliance Review Tool
- CRF CDE Review Response Tool

CDE Browser - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Media Print W Address http://cdebrowser-prod.nci.nih.gov/CDEBrowser/ Go

NATIONAL CANCER INSTITUTE **CADSR** **CDE Browser** **CDE Cart** **Home** **FormBuilder** **Help**

Data Element Search

Note: Enter/select search criteria and click search button to initiate search. The wildcard character is *. Click the Help button above for more information on CDEBrowser.

Search For: Permissible Value:

Value Domain: Clear Public ID:

Data Element Concept: Clear Classification: Clear

Version: Latest Version ☒ All Versions ☐ Context Use: Owned By/Used By

Workflow Status: ALL APPRVD FOR TRIAL USE CMTE APPROVED CMTE SUBMTD Search Field(s): ALL Long Name Preferred Name Document Text

User: Public User Version 2.1

National Institutes of Health (NIH) U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES FIRSTGOV Your First Click to the U.S. Government

<http://ncicb.nci.nih.gov/cdebrowser/>

Version 2.1

- *Released May 28, 2004*
- *CDE Cart*
- *Form Builder*
- *caDSR web site*
 - <http://ncicb.nci.nih.gov/core/caDSR>
- *caDSR Users Listserv*
 - http://list.nih.gov/archives/cadsr_users.html
- *CTEP Documentation*
 - <http://ncicb.nci.nih.gov/NCICB/core/caDSR/CTEPInformation>

Status of CTEP CDE Initiative

- *2400 approved CDEs*
 - *CTCAE v3.0*
 - *CDUS v3.0, release 2*
- *3200 terms awaiting review*
- Phase III studies
- Adult trials
- Clinical Trials Cooperative Groups
- Cancer Trials Support Unit

Future CTEP CDE Development

- *Quality of life*
- *Eligibility criteria*
- *Phase I and II trials*
- *Pediatric studies*

Harmonization

- *Business rules*
- *CDEs*
- *Training*
- *Registration status*

In Conclusion